

§ 820.46 Environmental control.

Where environmental conditions at the manufacturing site could have an adverse effect on a device's fitness for use, these environmental conditions shall be controlled to prevent contamination of the device and to provide proper conditions for each of the operations performed pursuant to § 820.40. Conditions to be considered for control are lighting, ventilation, temperature, humidity, air pressure, filtration, airborne contamination, and other contamination. Any environmental control system shall be periodically inspected to verify that the system is properly functioning. Such inspections shall be documented.

§ 820.56 Cleaning and sanitation.

There shall be adequate written cleaning procedures and schedules to meet manufacturing process specifications. Such procedures shall be provided to appropriate personnel.

(a) *Personnel sanitation.* Washing and toilet facilities shall be clean and adequate. Where special clothing requirements are necessary to assure that a device is fit for its intended use, clean dressing rooms shall be provided for personnel.

(b) *Contamination control.* There shall be procedures designed to prevent contamination of equipment, components, or finished devices by rodenticides, insecticides, fungicides, fumigants, hazardous substances, and other cleaning and sanitizing substances. Such procedures shall be documented.

(c) *Personnel practices.* Where eating, drinking, and smoking by personnel could have an adverse effect on a device's fitness for use, such practices shall be limited to designated areas selected so as to avoid such an adverse effect.

(d) *Sewage and refuse disposal.* Sewage, trash, by-products, chemical effluents, and other refuse shall be disposed of in a timely, safe, and sanitary manner.

Subpart D—Equipment**§ 820.60 Equipment.**

Equipment used in the manufacturing process shall be appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, and cleaning.

(a) *Maintenance schedule.* Where maintenance of equipment is necessary to assure that manufacturing specifications are met, a written schedule for the maintenance, adjustment, and cleaning of equipment shall be developed and adhered to. Such schedule shall be visibly posted on or near each piece of equipment, or be readily available to personnel performing maintenance activities. A written record shall be maintained documenting when scheduled maintenance activities are performed.

(b) *Inspection.* Periodic documented inspections shall be made to assure adherence to applicable equipment maintenance schedules.

(c) *Adjustment.* Any inherent limitations or allowable tolerances shall be visibly posted on or near equipment requiring periodic adjustments, or be readily available to personnel performing these adjustments.

(d) *Manufacturing material.* Manufacturing material, including a cleaning agent, mold-release agent, lubricating oil, or other substance used on or in the manufacturing equipment or the device, shall be subsequently removed from the device or limited to a specified amount that does not adversely affect the device's fitness for use. There shall be written procedures for the use and removal of such manufacturing material. The removal of such manufacturing material shall be documented.

§ 820.61 Measurement equipment.

All production and quality assurance measurement equipment, such as mechanical, automated, or electronic equipment, shall be suitable for its intended purposes and shall be capable of producing valid results. Such equipment shall be routinely calibrated, inspected, and checked according to written procedures. Records documenting these activities shall be maintained. When computers are used as part of an automated production or quality assurance system, the computer software programs shall be validated by adequate and documented testing. All program changes shall be made by a designated individual(s) through a formal approval procedure.

(a) *Calibration.* Calibration procedures shall include specific directions and limits for accuracy and precision. There shall be provisions for remedial action when accuracy and precision limits are not met. Calibration shall be performed by personnel having the necessary education, training, background, and experience.

(b) *Calibration standards.* Where practical, the calibration standards used for production and quality assurance measurement equipment shall be traceable to the national standards of the National Bureau of Standards, Department of Commerce. If national standards are not practical for the parameter being measured, an independent reproducible standard shall be used. If no applicable standard exists, an in-house standard shall be developed and used.

(c) *Calibration records.* The calibration date, the calibrator, and the next calibration date shall be recorded and displayed, or records containing such information shall be readily available for each piece of equipment requiring calibration. A designated individual(s) shall maintain a record of calibration dates and of the individual performing each calibration.

Subpart E—Control of Components

§ 820.80 Components.

Components used in manufacturing shall be received, stored, and handled in a manner designed to prevent damage, mixup, contamination, and other adverse effects. Components shall be quarantined prior to acceptance or clearly identified as not yet accepted.

(a) *Acceptance of components.* There shall be a written procedure for acceptance of components. A designated individual(s) shall accept or reject components. A record shall be maintained of component acceptance and rejection. Upon receipt, each shipping container of components shall be visually examined for damage. Where deviations from component specifications could result in the device being unfit for its intended use, components shall be inspected, sampled, and tested for conformance to specifications.

(b) *Storage and handling of components.* If the quality or fitness for use of components deteriorates over time, the components shall be stored in a manner to facilitate proper stock rotation. Component control numbers or other identifications shall be easily viewable. All obsolete, rejected, or deteriorated components shall be clearly identified and segregated from accepted components. Records shall be maintained of the disposition of all obsolete, rejected, or deteriorated components.

§ 820.81 Critical devices, components.

In addition to the requirements of § 820.80, the following requirements apply to critical devices:

(a) *Acceptance of critical components.* There shall be written procedures for the accepting, sampling, testing, and inspecting of all lots of critical components to assure that critical components conform to specifications. The number of units sampled from each lot of critical components shall be based upon an acceptable statistical rationale, the past quality history of the supplier, and the quantity needed for analysis and reserve. Each lot of critical components shall be identified with a control number(s) upon receipt. The percentage of defective critical components for each lot and the percentage of lots rejected shall be recorded and identified by supplier name.

(b) *Critical component supplier agreement.* Where possible, the manufacturer shall secure from the critical component supplier a written agreement whereby the supplier agrees to notify the manufacturer of any proposed change in a critical component. Where such an agreement exists, the manufacturer shall not accept such a change until the manufacturer has determined the impact of the change on the finished device.

Subpart F—Production and Process Controls

§ 820.100 Manufacturing specifications and processes.

Written manufacturing specifications and processing procedures shall be established, implemented, and controlled to assure that the device conforms to its original design or any approved changes in that design.

(a) *Specification controls.* (1) Procedures for specification control measures shall be established to assure that the design basis for the device, components, and packaging is correctly translated into approved specifications.

(2) Specification changes shall be subject to controls as stringent as those applied to the original design specifications of the device. Such changes shall be approved and documented by a designated individual(s) and shall include the approval date and the date the change becomes effective.

(b) *Processing controls.* (1) Where deviations from device specifications could occur as a result of the manufacturing process itself, there shall be written procedures describing any processing controls necessary to assure conformance to specifications.

(2) All processing control operations shall be conducted in a manner designed to assure that the device conforms to applicable specifications.

(3) There shall be a formal approval procedure for any change in the manufacturing process of a device. Any approved change shall be communicated to appropriate personnel in a timely manner.

§ 820.101 Critical devices, manufacturing specifications, and processes.

In addition to the requirements of § 820.100, the following requirements apply to critical devices:

(a) *Critical operation performance.* Any critical operation shall be performed by a suitable designated individual(s) or suitable equipment and shall be verified.

(b) *Record of critical operation.* Any individual responsible for the performance of a critical operation shall record or reference that operation in the device history record as required in § 820.185.

§ 820.115 Reprocessing of devices or components.

(a) Reprocessing procedures shall be established, implemented, and controlled to assure that the reprocessed device or component meets the original, or subsequently modified and approved, specifications.

(b) Any device rejected during finished device inspection and later reprocessed shall be subject to another complete final inspection for any characteristic of the device which may be adversely affected by such reprocessing.